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(54) Double sheath deployment system

Doppelhülliges Stenteinbringungssystem

Système de déployment de stent à double gaine

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Description

Field Of The Invention

[0001] This invention relates generally to medical devices and procedures, and more particularly to a method and system of deploying a stent-graft in a vascular system.

BACKGROUND OF THE INVENTION

[0002] Prostheses for implantation in blood vessels or other similar organs of the living body are, in general, well known in the medical art. For example, prosthetic vascular grafts formed of biocompatible materials (e.g., Dacron or expanded, porous polytetrafluoroethylene (PTFE) tubing) have been employed to replace or bypass damaged or occluded natural blood vessels. A graft material supported by framework is known as a stent-graft or endoluminal graft. In general, the use of stent-grafts for treatment or isolation of vascular aneurysms and vessel walls which have been thinned or thickened by disease (endoluminal repair or exclusion) are well known. Many stent-grafts, are "self-expanding", i.e., inserted into the vascular system in a compressed or contracted state, and permitted to expand upon removal of a restraint. Self-expanding stent-grafts typically employ a wire or tube configured (e.g. bent or cut) to provide an outward radial force and employ a suitable elastic material such as stainless steel or Nitinol (nickel-titanium). Nitinol may additionally employ shape memory properties. The self-expanding stent-graft is typically configured in a tubular shape of a slightly greater diameter than the diameter of the blood vessel in which the stent-graft is intended to be used. In general, rather than inserting in a traumatic and invasive manner, stent-grafts are preferably deployed through a less invasive intraluminal delivery, i.e., cutting through the skin to access a lumen or vasculature or percutaneously via successive dilatation, at a convenient (and less traumatic) entry point, and routing the stent-graft through the lumen to the site where the prosthesis is to be deployed.

[0003] Intraluminal deployment is typically effected using a delivery catheter with coaxial inner (plunger) and outer (sheath) tubes arranged for relative axial movement. The stent graft is compressed and disposed within the distal end of an outer catheter tube in front of an inner tube. The catheter is then maneuvered, typically routed though a lumen (e.g., vessel), until the end of the catheter (and the stent-graft) is positioned in the vicinity of the intended treatment site. The inner tube is then held stationary while the outer tube of the delivery catheter is withdrawn. The inner tube prevents the stent-graft from being withdrawn with the outer tube. As the outer tube is withdrawn, the stent-graft radially expands so that at least a portion of it is in substantially conforming surface contact with a portion of the interior of the lumen e.g., blood vessel wall.

[0004] Most stent-graft deployment systems use only a semi-rigid sheath in the deployment systems. The semi-rigid sheath provides columnar strength to advance the system through access vessels in the body. Unfortunately, the semi-rigid sheath may tend to kink in areas having tight radiuses such as the thoracic arch. Such kinking can increase the deployment force required to place a stent-graft in a target area or even prevent deployment completely. Even if kinking can be avoided, use of a semi-rigid sheath may still increase the pushing force needed to overcome frictional resistance required to deploy the stent-graft to the target area.

[0005] One attempt to overcome this problem by W.L. Gore utilized a flexible jacket that deploys the stent-graft with a ripcord that opens the jacket along the longitudinal axis of the flexible jacket, e.g., U.S. Patent 6,315,792. Another single step sheath release initiation is disclosed in U.S. Patent 5,824,041 to Lenker. Unfortunately, these methods introduced a separate non-integrated sheath into the system into the femoral artery and further failed to provide the desired control during deployment. Thus, a need exists for a method and deployment system that avoids kinking (reductions in area or change in shape which creates resistance to deployment) and reduces forces during deployment of stent-grafts in areas having tight radiuses, yet provides appropriate control and in addition provides flexibility during advancement in areas having tight radiuses.

[0006] US 2001/0034548 discloses a catheter with a double sheath, the inner sheath having a smaller diameter than the outer sheath.

SUMMARY OF THE INVENTION

[0007] In one aspect according to the present invention, a stent-graft deployment system comprises a retractable primary sheath, a secondary sheath initially covered by the retractable primary sheath, a stent-graft initially retained within the secondary sheath, and a deployment means for deploying the stent-graft. The secondary sheath is more flexible than the retractable primary sheath. The retractable primary sheath can contain the stent-graft in a first constrained small diameter configuration and the secondary sheath can be disposed within the retractable primary sheath and also contain the stent-graft. When the primary sheath is removed from around the stent-graft, the flexible secondary sheath contains the stent-graft in a second constrained small diameter configuration where the second diameter is greater than the first diameter. The removal of the secondary sheath releases the stent-graft from a radial constraint so that stent-graft deployment may proceed.

[0008] In another aspect according to the present invention, a stent-graft deployment system before deployment includes a stent-graft constricted within the flexible secondary sheath, a semi-rigid sheath around the flexible secondary sheath, the semi-rigid sheath being retracted to expose the flexible secondary sheath, and the flexible

secondary sheath being retractable such that the stent-graft expands as the flexible secondary sheath is retracted.

[0009] In another aspect according to the present invention, a device for implanting a radially self-expanding endoprosthesis comprises an outer sheath which is more rigid and axially maneuverable than an inner sheath. In one configuration the outer sheath is disposed over the inner sheath. While in a second position the outer sheath is retracted to expose the inner sheath. The device further comprises an axially maneuverable elongated catheter coupled to the inner sheath. In a first position the inner sheath retains the radially self-expanding endoprosthesis. As the inner sheath is moved to a second position by for example pulling the proximal end of the inner sheath, the radially self-expanding endoprosthesis is deployed.

[0010] A stent-graft deployment system, includes a stent-graft and a catheter having a catheter shaft having a tip; a retractable primary sheath and a retractable flexible secondary sheath. In a predeployed condition the flexible secondary sheath contains the stent-graft in a second constrained small diameter configuration around the catheter shaft at a stent graft location of the catheter near the tip and within the retractable primary sheath. When the primary sheath is retracted from around the stent-graft, the flexible secondary sheath containing the stent graft in the second constrained small diameter configuration is exposed and an end portion of the catheter from an end of the tip to a retracted end of the primary sheath has substantially reduced resistance to bending as compared to when the primary sheath is covering the stent graft location of the catheter. Removal of the secondary sheath releases the stent-graft from a radial constraint so that stent-graft deployment occurs as the secondary sheath releases. Removal of the retractable secondary sheath occurs through a secondary sheath retraction handle connected to a proximal end of the retractable flexible secondary sheath, such that retraction of the secondary sheath retraction handle causes a proximal end of the retractable flexible secondary sheath to be pulled along a catheter longitudinal axis toward a proximal end of the catheter. Pulling of the proximal end of the retractable flexible secondary sheath tensions the retractable flexible sheath to retract the sheath along the catheter longitudinal axis to cause progressive deployment of the stent graft from a distal end of the stent graft.

[0011] In another aspect described to illustrate use of the invention , a method of deploying a stent-graft includes the steps of loading the stent-graft deployment system with a stent-graft, tracking the stent-graft deployment system over a guide wire to a location before a target area which may include a curved portion, and retracting a primary sheath to expose a secondary sheath within said primary sheath while the primary sheath is retracted or held as the secondary sheath is exposed, the stent-graft is moved to its location within the target area or moved until its location within the target area is confirmed. The method further includes the steps of further tracking the stent-graft deployment system to place the secondary sheath in the curved portion of the target area, and retracting the secondary sheath to at least partially deploy the stent-graft in the target area and may include releasing the stent-graft from the delivery system using a release mechanism

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1 is a plan view of a stent-graft deployment system without a stent-graft in accordance with the present invention (not to scale);

[0013] FIG. 2 is a close up schematic plan view of the end of the deployment system of FIG. 1 having a loaded stent-graft;

[0014] FIG. 3 is a close up schematic plan view of the end of the deployment system of FIG. 1 showing an alternative retention mechanism with a loaded stent-graft;

[0015] FIG. 4 illustrates the stent-graft deployment system of FIG. 1 with a primary sheath covering a secondary sheath (in dashed lines);

[0016] FIG. 5 illustrates the stent-graft deployment system of FIG. 1 with the primary sheath retracted and the secondary sheath exposed;

[0017] FIG. 6 illustrates the stent-graft deployment system of FIG. 1 with the primary sheath retracted and the secondary sheath partially retracted;

[0018] FIG. 7 illustrates the stent-graft deployment system of FIG. 1 with the primary sheath retracted with the secondary sheath almost completely retracted;

[0019] FIG. 8 illustrates the stent-graft deployment system of FIG. 1 with the secondary sheath completely retracted and the stent-graft fully deployed;

[0020] FIG. 9 is a flow chart illustrating the steps of a method in accordance with the present invention;

[0021] FIG. 10 is a schematic diagram illustrating the stent-graft deployment system initially inserted to a location adjacent (before) a tight curved target area;

[0022] FIG. 11 is a schematic diagram illustrating the stent-graft deployment system showing the primary sheath retracted and the secondary sheath exposed;

[0023] FIG. 12 is a schematic diagram illustrating the stent-graft deployment system with the secondary sheath which is exposed advanced into the tight curve;

[0024] FIG. 13 is a schematic diagram illustrating the stent-graft deployment system with the secondary sheath which has been advanced into the curve is partially retracted and the stent-graft is partially deployed;

[0025] FIG. 14 is a schematic diagram illustrating the stent-graft deployment system with the secondary sheath being completely retracted and a stent-graft being fully deployed; and

[0026] FIG. 15 is a schematic diagram illustrating the stent-graft fully deployed with the stem-graft deployment system removed in accordance with the present invention.

DETAILED DESCRIPTION

[0027] FIGS. 1-3 show portions of a stent-graft deployment system 10. FIG. 1 illustrates the system 10 without a stent-graft while FIGS. 2 and 3 show close up views of the deployment system tip which are loaded with a stent-graft 15, 15a. This system could also deploy a stent alone or some other form of endoprosthesis. The subsequent use of "stent-graft" herein should be understood to include other forms of endoprosthesis. Ideally, the stent-graft deployment system 10 comprises a tapered tip 12, 12a, 12b that is flexible and able to provide trackability in tight and tortuous vessels, and can bend easily once the primary sheath 20 is retracted. Other tip shapes such as bullet-shaped tips could also be used.

[0028] The system 10 includes a primary sheath 20 (preferably made of a semi-rigid material such as PTFE) initially covering a secondary sheath 14 (preferably made of woven polyethylene terephthalate (PET)). The secondary sheath 14 is more flexible than the retractable primary sheath 20. The deployment system 10 is able to separately retract the primary and secondary sheaths.

[0029] The primary sheath should have enough stiffness to provide adequate trackability and column strength as the system 10 tracks through tortuous vessels to avoid buckling or kinking. The secondary sheath utilizes its greater flexibility (at the expense of column strength) to improve trackability and pushability, particularly through areas having tight radiuses. So, where prior deployment systems utilizing just a semi-rigid primary sheath were prone to kinking while tracking through an area with a tight radius. Use of the secondary sheath avoids kinking or changes in shape and reduces resistance to deployment (reduced advancement force) while tracking through vessels with tight curves.

[0030] The deployment system 10 also includes a stent-graft 15 initially retained within the secondary sheath 14. As described herein, the stent-graft 15 is preferably a self-expanding, Nitinol/Dacron stent-graft system designed for endovascular exclusion of Thoracic Aortic Aneurisms (TAA). The deployment system 10 includes a cup 16 as shown in FIG. 2 or alternatively steel runners 17 as shown in FIG. 3 that eventually release the stem-graft by its mere self-expansion to act as a means for retaining the stent-graft 15 in place during deployment. Although the means for retaining shown in FIG. 3 is on the "backend" of the stent-graft, it can alternatively or additionally be on a "tip end" of the stent-graft and attached to one or more of several coaxial tubes. A handle or a hub 22 is fixed to the primary sheath 20, a second handle or hub (24) near a proximal end of the stent-graft deployment system 10 is fixed to the secondary sheath, and a catheter shaft including a shaft handle 26 is connected to and aids the advancement of the system 10 and acts as a deployment means. In addition, the deployment system 10 shown includes a flush port 28 and a radiopaque marker 18 allowing for accurate positioning of the delivery system prior to deployment of the stent-graft in the proximal position.

[0031] Referring to FIGS. 4-8 and FIGS. 10-15, the stent-graft deployment system 10 is shown in various stages as it is advances over a guide wire 111 (as shown in FIGS. 10-14) and the stent-graft is deployed. FIGS. 4-8, in particular, illustrate the stent-graft deployment system 10 as it would operate or function outside or apart from the body. FIGS. 10-15 illustrate the stent-graft deployment system as it would operate when tracking over a guide wire 111 within a body and particularly through a target area (vessel) having a tight curvature or radius (21). FIGS. 4 and 10 both illustrate the stent-graft deployment system 10 with the primary sheath 20 covering the secondary sheath 14. The flexible secondary sheath 14 is arranged within the semi-rigid sheath 20 when the semi-rigid sheath 20 is in a non-retracted position as shown in FIG. 4.

[0032] As shown in FIG. 5, the stent-graft 15 is constrained solely by the flexible secondary sheath 14 and further illustrates a handle or hub 22 coupled to the semi-rigid sheath 20 serving as a first arrangement for retracting the semi-rigid sheath 20 and exposing the flexible secondary sheath 14 as well as an inner tube 25 coupled to the flexible secondary sheath 14 serving as a second arrangement for retracting the flexible secondary sheath and enabling the stent-graft to expand. It should be noted that the exposed portion of the flexible secondary sheath 14 has a diameter larger than the semi-rigid primary sheath 20 that surrounded the flexible secondary sheath 14 previously. The larger diameter of the exposed portion of the flexible secondary sheath 14 is a contributory factor in reducing the force needed to retract the secondary sheath. Once the flexible secondary sheath 14 is exposed, the end of stent-graft deployment system 10 beyond the semi-rigid sheath has greater flexibility (than the portion of the system within the semi-rigid sheath 20) as it tracks across the guidewire.

[0033] The first arrangement described above could comprise (as previously mentioned) the handle or hub 22 coupled to the semi-rigid sheath 20 enabling the relative axial movement of the semi-rigid sheath 20 over a remainder of the stent-graft deployment system and the second arrangement could comprise an inner tube 25 coupled to the flexible secondary sheath 14 that enables relative axial movement of the flexible secondary sheath 14 relative to the semi-rigid sheath 20 and the longitudinal axis of the catheter. Such as where operation of the second handle 24 causes axial pulling of the proximal end of the flexible secondary sheath 14, to create a tension in the material/fabric of the secondary sheath to cause retraction that causes the cylindrically configured sheath to retract along the longitudinal axis of the catheter to provide a substantially circularly uniform deployment of the stent graft starting at its distal end (relative to the catheter).

[0034] In any event, once the secondary sheath 14 is exposed or outside the primary sheath, the system 10 can be advanced over the guide wire 111 with a lower

advancement force since the secondary sheath is designed to be quite flexible particularly in areas with tight radiuses (2 1) as shown in FIG. 12. The tight arch 21 is meant to represent any area or vessels with tight radiuses such as the thoracic arch.

[0035] Referring to FIGS. 6 and 13, in each instance the primary sheath has been retracted and the secondary sheath is shown partially retracted with the stent-graft 15 being partially deployed. As the secondary sheath retracts, more and more of the stent-graft is deployed as shown in FIGS. 6-8 and FIGS. 13-15.

[0036] FIGS. 8 and 14 illustrate the stent-graft deployment system 10 with the secondary sheath 14 completely retracted and the stent-graft 15 fully deployed. In FIG. 15 the stent-graft deployment system 10 has been removed.

[0037] The stent-graft deployment system 10 can also be thought of as a device for implanting a radially self-expanding endoprosthesis 15 having an outer sheath 20. As previously explained, the outer sheath 20 is more rigid and axially maneuverable relative to an inner sheath 14 and wherein the outer sheath 20 is disposed over the inner sheath 14 in a first position (as shown in FIG. 5) and exposes the inner sheath 14 in a second position (as shown in FIGS. 6-8). The system 10 can also include an elongated catheter 25 coupled to the inner sheath 14, wherein the inner sheath 14 is constructed to retain the radially self-expanding endoprosthesis 15 in a first position and enable deployment of the radially self-expanding endoprosthesis 15 in a second position.

[0038] Referring to FIG. 9, a flow chart illustrates a method 100 of deploying a stent-graft includes the steps of providing a stent-graft deployment system with a stent-graft 102, tracking the stent-graft deployment system over a guide wire to a location before a target area 104, which may include a curved portion, and retracting the primary sheath to expose a secondary sheath within the target area while the primary sheath is retracted or held as the secondary sheath is exposed 106. The stent-graft is moved to its location within the target area or until its location within the target area is confirmed. It should be noted that once the primary sheath is retracted and the secondary sheath is exposed, the secondary sheath (being of a relatively more flexible material than the primary sheath) will provide greater flexibility in tracking through the remainder of the target area regardless of the curvature or tortuous nature of the vessel. The method further includes the steps of further tracking the stent-graft deployment system to place the secondary sheath in the curved portion of the target area 108, and retracting the secondary sheath to at least partially deploy the stent-graft in the target area 110. This step may include deploying or releasing the stent-graft from the delivery system using a release mechanism 112.

[0039] The device may also be considered to have a first predeployment configuration wherein said first and second sheaths surround the stent graft to be deployed, and a second partial deployment configuration where the primary sheath is fully retract so that the primary sheath no longer constrains the stent graft to be deployed, while the secondary sheath still constrains the stent graft to be deployed, and third fully deployed configuration where said stent graft is fully released from the primary and secondary sheaths. Wherein the relative movement of the tubular (substantially cylindrical sheaths) is such that the axial centerline of the cylinder forming the sheaths is moved without the sheaths being everted between their respective predeployment configurations and their respective post deployment configurations such that the axial centerline of the cylinder of each sheath moves in substantially one motion (in a linear movement along a curving path) along the axial centerline of the catheter along which it is moved

[0040] The present configuration is well suited for introducing the stent-graft deployment system into a femoral artery and advancing the stent-graft deployment system through an iliac artery into the aorta for repair of an aortic aneurysm and more specifically in tracking the stent-graft deployment system through a portion of an thoracic arch when the secondary sheath has been exposed after the retraction of the primary sheath and without any kinking of the primary sheath.

[0041] Additionally, the description above is intended by way of example only and is not intended to limit the scope of the invention and its equivalents as understood by persons skilled in the art and defined in the claims.

Claims

1. A stent-graft deployment system, comprising:

    a stent-graft (15);
    a catheter, comprising:

        a catheter shaft having a tip (12);
        a retractable primary sheath (20) and a retractable flexible secondary sheath (14);

    wherein in a first predeployed condition said flexible secondary sheath (14) contains said stent-graft (15) around said catheter shaft at a stent graft location of said catheter near said tip and within said retractable primary sheath (20) diameter, wherein in a second predeployed configuration when said primary sheath (20) is fully retracted from around said stent-graft (15) and said flexible secondary sheath (14), said flexible secondary sheath (14) containing said stent graft (15) is exposed and contains said stent-graft (15) within a secondary sheath (14) diameter, wherein removal of the secondary sheath (14) releases the stent-graft (15) from a radial constraint so that stent-graft deployment occurs as the secondary sheath (14) releases, **characterised in that** said secondary sheath (14) diameter is larger than said primary sheath (20)

diameter.

2. The stent graft deployment system as in Claim 1, wherein removal of the retractable secondary sheath (14) occurs through a secondary sheath retraction member (24) connected to a proximal end of said retractable flexible secondary sheath (14), such that retraction of the secondary sheath retraction member (24) causes a proximal end of said retractable flexible secondary sheath (14) to be pulled along a catheter longitudinal axis toward a proximal end of said catheter, where pulling of the proximal end of said retractable flexible secondary sheath (14) creates a force to tension the retractable flexible sheath to cause a retraction of the secondary sheath (14) along the catheter longitudinal axis thereby causing progressive deployment of said stent graft (15) from the distal end of the catheter.

3. The stent-graft deployment system of claim 1 or 2, wherein the secondary sheath (14) diameter is slightly larger than said primary sheath (20) diameter.

4. The stent-graft deployment system of any of the preceding claims, wherein the retractable primary sheath (20) is comprised of a semi-rigid material such as PTFE.

5. The stent-graft deployment system of any of the preceding claims, wherein the secondary sheath (14) is selected from the group of materials comprising woven materials such as fabrics, porous materials such as ePTFE, polymers such as ultra thin walled polymers, and flexible materials such as PET.

6. The stent-graft deployment system according to claim 1,
wherein said retractable primary sheath (20) diameter is considered to be a first constrained diameter configuration;
wherein said secondary sheath (14) diameter is considered to be a second constrained diameter configuration, selectively disposed within the retractable primary sheath (20),
wherein the secondary sheath (14) is more flexible than the retractable primary sheath (20).

7. The stent-graft deployment system of claim 6, wherein the system further comprises a taper tip (12) at a distal end of the catheter shaft.

8. The stent-graft deployment system of claim 6 or 7, wherein the system further comprises a retention means for retaining the stent-graft (15).

9. The stent-graft deployment system of any of claims 6 to 8, wherein the secondary sheath (14) is selectively disposed within the retractable primary sheath (20) by axially retracting the primary sheath (20) relative to the secondary sheath (14).

10. The stent-graft deployment system according to claim 1,
whereon said primary sheath (20) is a semi-rigid sheath;
wherein said secondary sheath (14) is coaxially arranged within the semi-rigid sheath when the semi-rigid sheath is in said predeployed condition which is a non-retracted position;
wherein said stent-graft (15) is disposed collapsed within the flexible secondary sheath (14);
further comprising:

an arrangement (26) for retracting the semi-rigid sheath (20) and exposing the flexible secondary sheath (14);

a second arrangement (24) for retracting the flexible secondary sheath (14), wherein the stent-graft (15) is able to expand towards complete deployment as the flexible secondary sheath is removed by being retracted.

11. The stent-graft deployment system of claim 10, wherein the stent-graft system further comprises a taper tip (12).

12. The stent-graft deployment system of claim 10 or 11, wherein the arrangement (26) for retracting the semi-rigid sheath (20) comprises a hub (22) coupled to the semi-rigid sheath (20) enabling relative axial movement of the semi-rigid sheath (20) over a remainder of the stent-graft deployment system (10).

13. The stent-graft deployment system of any of claims 10 to 12, wherein the arrangement (24) for retracting the flexible secondary sheath (14) comprises moving an inner tube coupled to the flexible secondary sheath (14) that enables relative axial movement of the flexible secondary sheath (14) relative to the semi-rigid sheath (20).

14. The stent graft deployment system according to any of the preceding claims,
wherein the deployment system (10) includes a cup (16) for retaining the stent-graft (15) in place during deployment.

15. The stent graft deployment system according to any of claims 1 to 13,
wherein the deployment system (10) includes steel runners (17) for retaining the stent-graft (15) in place during deployment.

16. The stent graft deployment system according to any of claims 1 to 15, wherein

said primary sheath (20) is more rigid and axially maneuverable relative to said secondary sheath (14) and wherein the primary sheath (20) is disposed over the secondary sheath (14) in a first position and exposes the secondary sheath (14) in a second position; and
the elongated catheter is coupled to the secondary sheath (14) and axially maneuverable, wherein the secondary sheath (14) is constructed to retain the radially self-expanding stent-graft (15) in a first position and enable deployment of the radially self-expanding stent-graft (15) in a second position.

Patentansprüche

1. Stent-Graft-Entfaltungssystem, umfassend:

   einen Stent-Graft (15)
   einen Katheter, umfassend:

      einen Katheterschaft, der eine Spitze (12) aufweist;
      eine zurückziehbare erste Hülle (20) und eine zurückziehbare, elastische zweite Hülle (14);

   wobei in einem ersten Zustand vor dem Entfalten die elastische zweite Hülle (14) den Stent-Graft (15) um den Katheterschaft herum in einer Stent-Graft-Position des Katheters in der Nähe der Spitze und innerhalb des Durchmessers der ersten zurückziehbaren Hülle (20) enthält, wobei in einer zweiten Konfiguration vor der Entfaltung, wenn die erste Hülle (20) vollständig rings um den Stent-Graft (15) und von der elastischen zweiten Hülle (14) zurückgezogen ist, die elastische zweite Hülle (14), die den Stent-Graft (15) enthält, freigelegt ist und den Stent-Graft (15) innerhalb des Durchmessers der zweiten Hülle (14) enthält, wobei das Entfernen der zweiten Hülle (14) den Stent-Graft (15) aus einer radialen Einschränkung derart entlässt, dass das Entfalten des Stent-Grafts stattfindet, während ihn die zweite Hülle freisetzt, **dadurch gekennzeichnet, dass** der Durchmesser der zweiten Hülle (14) größer als der Durchmesser der ersten Hülle (20) ist.

2. Stent-Graft-Entfaltungssystem nach Anspruch 1, wobei das Entfernen der zurückziehbaren zweiten Hülle (14) mittels eines Rückzugselementes (24) der zweiten Hülle stattfindet, die an dem proximalen Ende der zurückziehbaren elastischen zweiten Hülle (14) derart befestigt ist, dass das Zurückziehen des Rückzugselements (24) der zweiten Hülle einen Zug an dem proximalen Ende der zurückziehbaren elastischen zweiten Hülle (14) entlang einer Längsachse des Katheters in Richtung auf das proximale Ende des Katheters bedingt, wobei das Ziehen an dem proximalen Ende der zurückziehbaren elastischen zweiten Hülle (14) eine Kraft erzeugt, die die zurückziehbare elastische Hülle spannt, um ein Zurückziehen der zweiten Hülle (14) entlang der Längsachse des Katheters zu verursachen, wodurch von dem distalen Ende des Katheters ausgehend eine schrittweise Entfaltung des Stent-Grafts (15) bewirkt wird.

3. Stent-Graft-Entfaltungssystem nach Anspruch 1 oder 2, wobei der Durchmesser der zweiten Hülle (14) geringfügig größer als der Durchmesser der ersten Hülle (20) ist.

4. Das Stent-Graft-Entfaltungssystem nach einem der vorhergehenden Ansprüche, wobei die zurückziehbare erste Hülle (20) aus einem halbsteifen Material wie PTFE besteht.

5. Das Stent-Graft-Entfaltungssystem nach einem der vorangehenden Ansprüche, wobei die zweite Hülle (14) ausgewählt ist aus der Gruppe von Materialien, die gewebte Materialien wie etwa Gewebe, poröse Materialien wie etwa ePTFE, Polymere wie etwa ultradünnwandige Polymere und elastische Materialien wie etwa PET umfassen.

6. Das Stent-Graft-Entfaltungssystem nach Anspruch 1, wobei der Durchmesser der ersten zurückziehbaren Hülle (20) als eine erste eingeschränkte Durchmesser-Konfiguration gilt; wobei der Durchmesser der zweiten Hülle (14) als eine zweite eingeschränkte Durchmesser-Konfiguration gilt, die wahlweise innerhalb der zurückziehbaren ersten Hülle (20) angeordnet ist, wobei die zweite Hülle (14) elastischer als die zurückziehbare erste Hülle (20) ist.

7. Das Stent-Graft-Entfaltungssystem nach Anspruch 6, wobei das System ferner eine konische Spitze (12) an dem distalen Ende des Katheterschafts umfasst.

8. Das Stent-Graft-Entfaltungssystem nach Anspruch 6 oder 7, wobei das System ferner ein Haltemittel zum Zurückhalten des Stent-Grafts (15) umfasst.

9. Das Stent-Graft-Entfaltungssystem nach einem der Ansprüche 6 bis 8, wobei die zweite Hülle (14) wahlweise innerhalb der zurückziehbaren ersten Hülle (20) durch axiales Zurückziehen der ersten Hülle (20) relativ zu der zweiten Hülle (14) angeordnet ist.

10. Das Stent-Graft-Entfaltungssystem nach Anspruch 1, wobei die erste Hülle (20) eine halbsteife Hülle ist; wobei die zweite Hülle (14) koaxial innerhalb der halbsteifen Hülle angeordnet ist, wenn die halbsteife Hülle sich in dem Zustand vor der Entfaltung befindet, die eine nicht zurückgezogene Position ist;

wobei der Stent-Graft (15) zusammengefaltet innerhalb der elastischen zweiten Hülle (14) angeordnet ist;
ferner umfassend:

eine Anordnung (26) zum Zurückziehen der halbsteifen Hülle (20) und zum Freilegen der elastischen zweiten Hülle (14);
eine zweite Anordnung (24) zum Zurückziehen der elastischen zweiten Hülle (14), wobei der Stent-Graft (15) in der Lage ist, sich vollständig zu entfalten, während die elastische zweite Hülle durch Zurückziehen entfernt wird.

11. Das Stent-Graft-Entfaltungssystem nach Anspruch 10, wobei das Stent-Graft-System ferner eine konische Spitze (12) umfasst.

12. Das Stent-Graft-Entfaltungssystem nach Anspruch 10 oder 11, wobei die Anordnung (26) zum Zurückziehen der halbsteifen Hülle (20) ein Griffstück (22) umfasst, das an die halbsteife Hülle (20) gekoppelt ist, was eine relative axiale Bewegung der halbsteifen Hülle (20) über einen Rest des Stent-Graft-Entfaltungssystems ermöglicht.

13. Das Stent-Graft-Entfaltungssystem nach einem der Ansprüche 10 bis 12, wobei die Anordnung (24) zum Zurückziehen der zweiten Hülle (14) das Bewegen eines Innenrohres, das an die elastische zweite Hülle (14) gekoppelt ist, umfasst, was eine relative axiale Bewegung der elastischen zweiten Hülle (14) bezüglich der halbsteifen Hülle (20) ermöglicht.

14. Das Stent-Graft-Entfaltungssystem nach einem der vorangehenden Ansprüche, wobei das Entfaltungssystem (10) einen Außenring (16) enthält, der während des Entfaltens den Stent-Graft (15) an der Stelle hält.

15. Das Stent-Graft-Entfaltungssystem nach einem der Ansprüche 1 bis 13, wobei das Entfaltungssystem (10) eine Führungsschiene aus Stahl (17) enthält, die während des Entfaltens den Stent-Graft (15) an der Stelle hält.

16. Das Stent-Graft-Entfaltungssystem nach einem der Ansprüche 1 bis 15, wobei die erste Hülle (20) steifer und relativ zu der zweiten Hülle (14) axial manövrierbar ist und wobei die erste Hülle (20) in einer ersten Position über der zweiten Hülle (14) angeordnet ist und in einer zweiten Position die zweite Hülle (14) freilegt; und
der verlängerte Katheter an die zweite Hülle (14) gekoppelt und axial manövrierbar ist, wobei die zweite Hülle (14) ausgebildet ist, den radial selbstexpandierenden Stent-Graft (15) in einer ersten Position zu fixieren und die Einführung des radial selbstexpandierenden Stent-Grafts (15) in einer zweiten Position zu ermöglichen.

Revendications

1. Système de déploiement de greffon à stent, comprenant :

un greffon à stent (15) ;
un cathéter comprenant :

une tige de cathéter dotée d'une pointe (12) ;
une gaine primaire rétractable (20) et une gaine secondaire flexible rétractable (14) ;

dans lequel, dans une première position pré-déployée, ladite gaine secondaire flexible (14) contient ledit greffon à stent (15) autour de ladite tige de cathéter à un emplacement de greffon à stent dudit cathéter près de ladite pointe et dans le diamètre de ladite gaine primaire rétractable (20), dans lequel, dans une deuxième configuration pré-déployée, lorsque ladite gaine primaire (20) est totalement rétractée depuis le tour dudit greffon à stent (15) et de ladite gaine secondaire flexible (14), ladite gaine secondaire flexible (14) contenant ledit greffon à stent (15) est exposée et contient ledit greffon à stent (15) dans un diamètre de gaine secondaire (14), l'enlèvement de la gaine secondaire (14) libérant le greffon à stent (15) d'une contrainte radiale, de sorte que le déploiement du greffon à stent (15) a lieu lorsque la gaine secondaire (14) se libère, **caractérisé en ce que** le diamètre de ladite gaine secondaire (14) est supérieur au diamètre de ladite gaine primaire (20).

2. Système de déploiement de greffon à stent selon la revendication 1, dans lequel l'enlèvement de la gaine secondaire rétractable (14) est assuré par un élément de rétraction de gaine secondaire (24) connecté à une extrémité proximale de ladite gaine secondaire flexible rétractable (14), de sorte que la rétraction de l'élément de rétraction de gaine secondaire (24) a pour effet qu'une extrémité proximale de ladite gaine secondaire flexible rétractable (14) est tirée le long d'un axe longitudinal du cathéter vers une extrémité proximale dudit cathéter, où la traction de l'extrémité proximale de ladite gaine secondaire flexible rétractable (14) crée une force afin de tendre la gaine flexible rétractable pour entraîner une rétraction de la gaine secondaire (14) le long de l'axe longitudinal du cathéter, ce qui entraîne le déploiement progressif dudit greffon à stent (15) depuis l'extrémité distale du cathéter.

3. Système de déploiement de greffon à stent selon la revendication 1 ou 2, dans lequel le diamètre de la gaine secondaire (14) est légèrement supérieur au diamètre de ladite gaine primaire (20).

4. Système de déploiement de greffon à stent selon l'une quelconque des revendications précédentes, dans lequel la gaine primaire rétractable (20) est composée d'un matériau semi-rigide comme du PTFE.

5. Système de déploiement de greffon à stent selon l'une quelconque des revendications précédentes, dans lequel la gaine secondaire (14) est sélectionnée parmi le groupe de matériaux comprenant des matériaux tissés comme des tissus, des matériaux poreux comme de l'ePTFT, des polymères comme des polymères à parois ultrafines et des matériaux flexibles comme du PET.

6. Système de déploiement de greffon à stent selon la revendication 1,
dans lequel le diamètre de ladite gaine primaire rétractable (20) est considéré comme étant une première configuration à diamètre contraint ;
dans lequel le diamètre de ladite gaine secondaire (14) est considéré comme étant une deuxième configuration à diamètre contraint disposée sélectivement dans la gaine primaire rétractable (20), la gaine secondaire (14) étant plus flexible que la gaine primaire rétractable (20).

7. Système de déploiement de greffon à stent selon la revendication 6, dans lequel le système comprend en outre une pointe effilée (12) à une extrémité distale de la tige de cathéter.

8. Système de déploiement de greffon à stent selon la revendication 6 ou 7, dans lequel le système comprend en outre un moyen de rétention pour retenir le greffon à stent (15).

9. Système de déploiement de greffon à stent selon l'une quelconque des revendications 6 à 8, dans lequel la gaine secondaire (14) est disposée sélectivement dans la gaine primaire rétractable (20) en rétractant axialement la gaine primaire (20) par rapport à la gaine secondaire (14).

10. Système de déploiement de greffon à stent selon la revendication 1,
dans lequel ladite gaine primaire (20) est une gaine semi-rigide ;
dans lequel ladite gaine secondaire (14) est disposée coaxialement dans la gaine semi-rigide lorsque la gaine semi-rigide est dans ladite position pré-déployée qui est une position non rétractée ;
dans lequel ledit greffon à stent (15) est disposé aplati à l'intérieur de la gaine flexible secondaire (14) ;
comprenant en outre :

un dispositif (26) de rétraction de la gaine semi-rigide (20) et d'exposition de la gaine flexible secondaire (14) ;
un deuxième dispositif (24) de rétraction de la gaine flexible secondaire (14), le greffon à stent (15) étant apte à se dilater en déploiement complet lorsque la gaine flexible secondaire est enlevée en la rétractant.

11. Système de déploiement de greffon à stent selon la revendication 10, dans lequel le système de greffon à stent comprend en outre une pointe effilée (12).

12. Système de déploiement de greffon à stent selon la revendication 10 ou 11, dans lequel le dispositif (26) de rétraction de la gaine semi-rigide (20) comprend une plate-forme (22) couplée à la gaine semi-rigide (20) et permettant un mouvement axial relatif de la gaine semi-rigide (20) au dessus du reste du système de déploiement de greffon à stent (10).

13. Système de déploiement de greffon à stent selon l'une quelconque des revendications 10 à 12, dans lequel le dispositif (24) de rétraction de la gaine flexible secondaire (14) comprend un déplacement d'un tube interne couplé à la gaine flexible secondaire (14) qui permet un mouvement axial relatif de la gaine flexible secondaire (14) par rapport à la gaine semi-rigide (20).

14. Système de déploiement de greffon à stent selon l'une quelconque des revendications précédentes, dans lequel le système de déploiement (10) comprend une coupelle (14) pour retenir le greffon à stent (15) en place pendant le déploiement.

15. Système de déploiement de greffon à stent selon l'une quelconque des revendications 1 à 13,
dans lequel le système de déploiement (10) comprend des chenaux en acier (17) pour retenir le greffon à stent (15) en place pendant le déploiement.

16. Système de déploiement de greffon à stent selon l'une quelconque des revendications 1 à 15,
dans lequel ladite gaine primaire (20) est plus rigide et est manoeuvrable axialement par rapport à ladite gaine secondaire (14) et dans lequel la gaine primaire (20) est disposée au dessus de la gaine secondaire (14) dans une première position et expose la gaine secondaire (14) dans une deuxième position ; et
le cathéter allongé est couplé à la gaine secondaire (14) et manoeuvrable axialement, la gaine secondaire (14) étant conçue de manière à retenir le greffon à stent s'auto-dilatant radialement (15) dans une

première position et à permettre le déploiement du greffon à stent s'auto-dilatant radialement (15) dans une deuxième position.

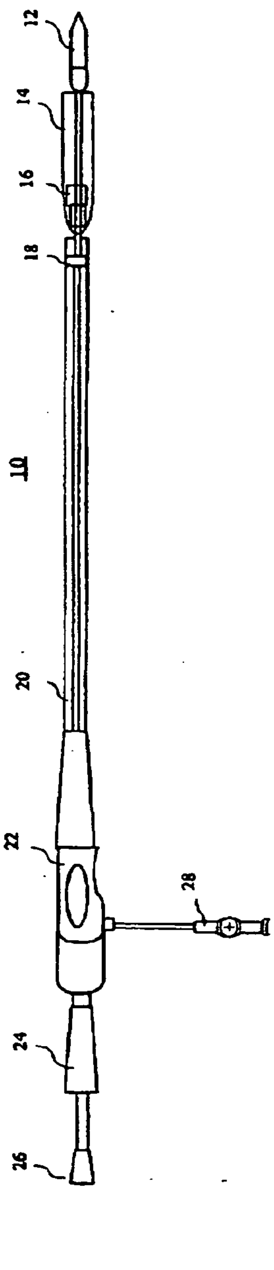


FIG. 1

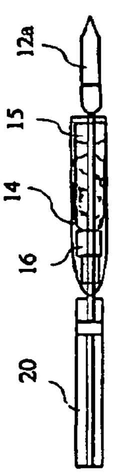


FIG. 2

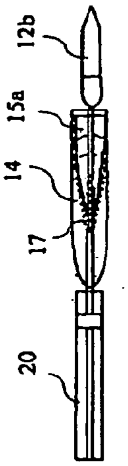


FIG. 3

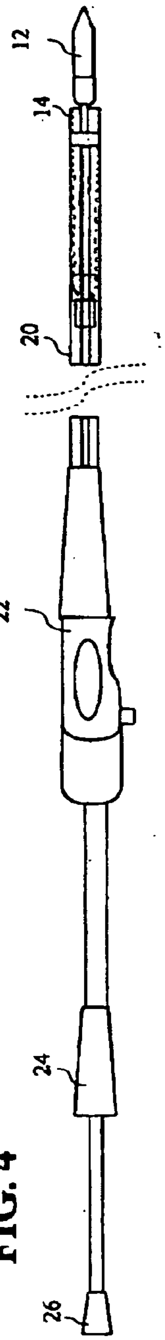


FIG. 4

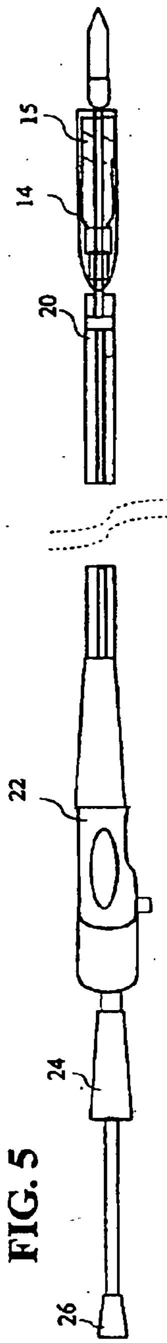


FIG. 5

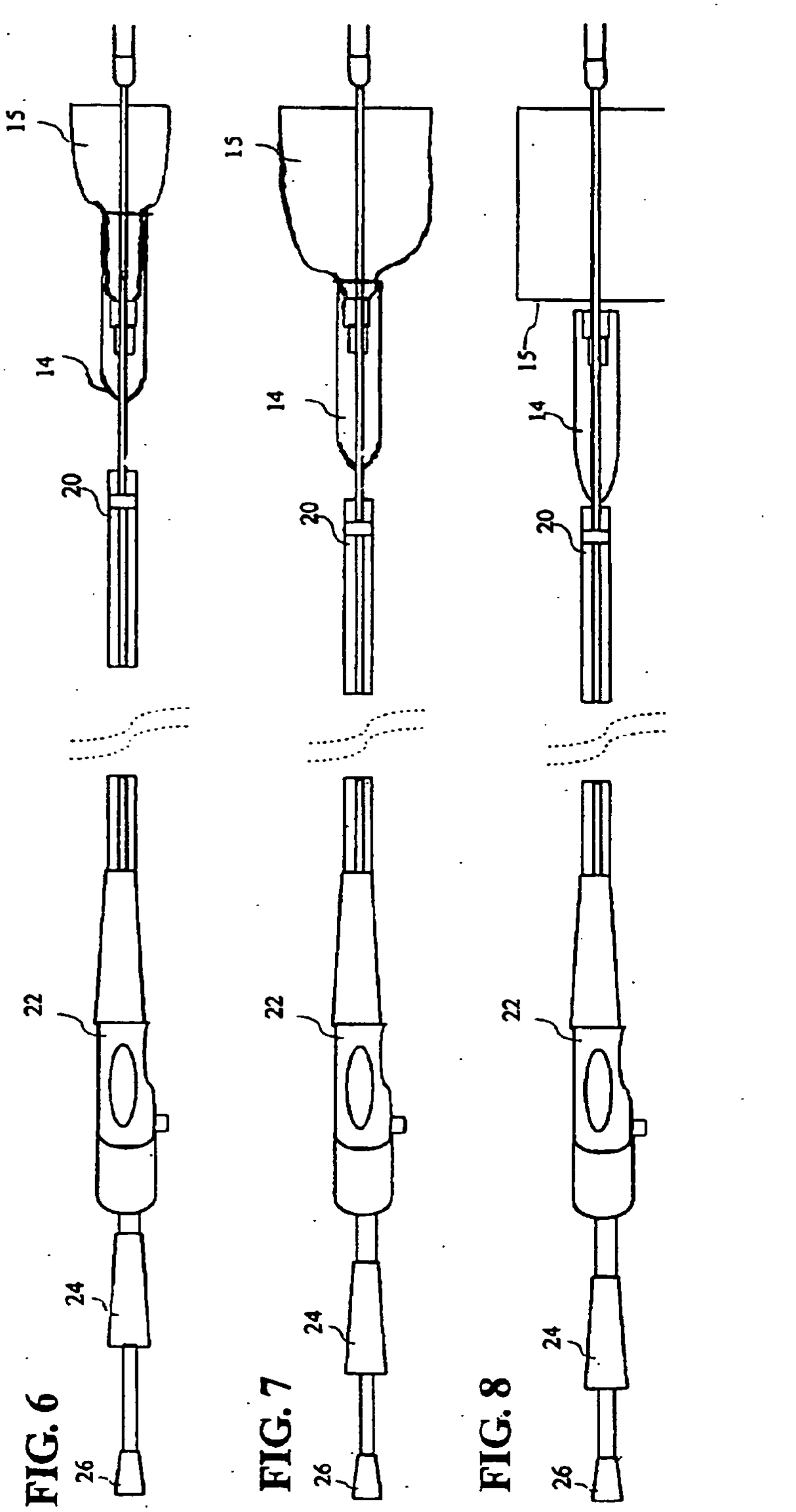
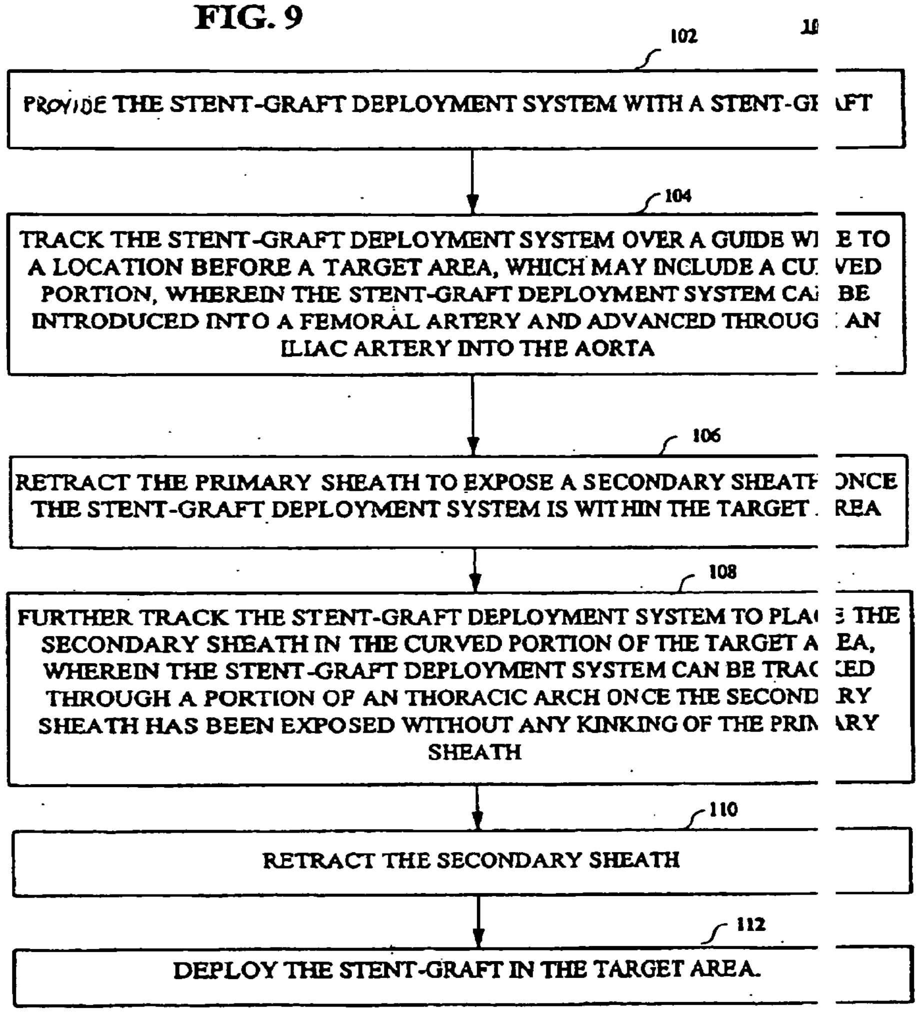


FIG. 6

FIG. 7

FIG. 8

FIG. 9


102
PROVIDE THE STENT-GRAFT DEPLOYMENT SYSTEM WITH A STENT-GI ΛFT
104
TRACK THE STENT-GRAFT DEPLOYMENT SYSTEM OVER A GUIDE WI E TO A LOCATION BEFORE A TARGET AREA, WHICH MAY INCLUDE A CU VED PORTION, WHEREIN THE STENT-GRAFT DEPLOYMENT SYSTEM CA BE INTRODUCED INTO A FEMORAL ARTERY AND ADVANCED THROUG AN ILIAC ARTERY INTO THE AORTA
106
RETRACT THE PRIMARY SHEATH TO EXPOSE A SECONDARY SHEATH ONCE THE STENT-GRAFT DEPLOYMENT SYSTEM IS WITHIN THE TARGET REA
108
FURTHER TRACK THE STENT-GRAFT DEPLOYMENT SYSTEM TO PLA THE SECONDARY SHEATH IN THE CURVED PORTION OF THE TARGET A EA, WHEREIN THE STENT-GRAFT DEPLOYMENT SYSTEM CAN BE TRA ED THROUGH A PORTION OF AN THORACIC ARCH ONCE THE SECOND RY SHEATH HAS BEEN EXPOSED WITHOUT ANY KINKING OF THE PRIN ARY SHEATH
110
RETRACT THE SECONDARY SHEATH
112
DEPLOY THE STENT-GRAFT IN THE TARGET AREA.

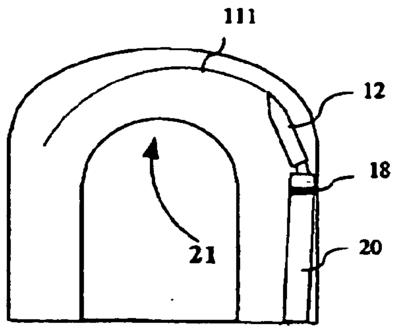


FIG. 10

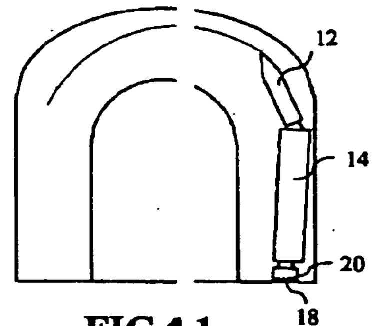


FIG. 11

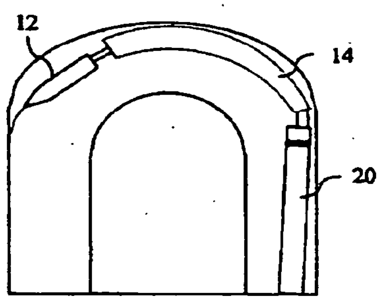


FIG. 12

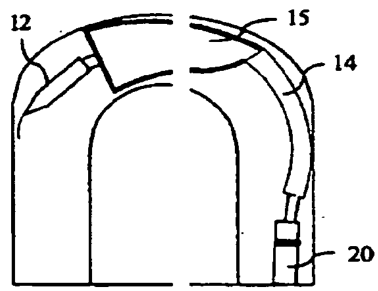


FIG. 13

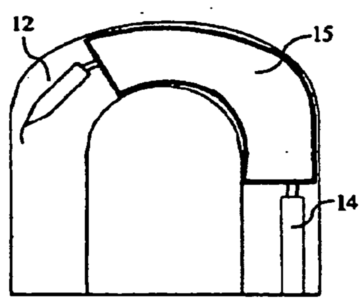


FIG. 14

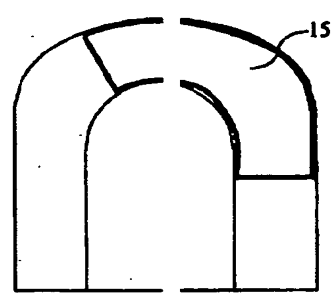


FIG. 15

REFERENCES CITED IN THE DESCRIPTION

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